REMARKS

Claims 1-6, 9, 12, 17, 21-23, 26-34, 37 and 52, were pending. By this Amendment claim 1 has been amended and claims 33, 37 and 52 have been canceled. Claims 1-6, 9, 12, 17, 21-23, 26-30 and 34 are now pending and under examination. Withdrawn claims 31-32 are being maintained of record pending the filing of one or more divisional applications.

Support for the amendment of claim 1 may be found, *inter alia,* in canceled original claim 33. Applicants maintain that the amendment does not raise an issue of new matter. Entry of this Amendment is respectfully requested.

The status of the claims reflected on pages 1-2 of the Office Action is incorrect. Claims 18-20 were canceled by the December 20, 2004 Preliminary Amendment. Page 2 of the Action, first paragraph, refers to a "preliminary amendment filed on 11/20/2004". The Preliminary Amendment was filed on December 20, 2004, not November 20, 2004.

NO OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 1-6, 26, 27, 29, 30, 34, 37 and 52 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-7 and 11-12 of copending Application No. 10/547,654 in view of WO 94/25627 A1.

Claims 1-5, 29, 30, 33, 34 and 52 have been provisionally rejected for alleged obviousness-type double patenting over claims 1-9, 14-15 and 18-19 of copending Application No. 10/548,057 in view of WO 94/25627 A1.

Claims 1-5, 29, [30], 33, 34 and 52 have been provisionally rejected for alleged obviousness-type double patenting over claims 13 and 16-17 of copending Application No. 10/700,143 in view of WO 94/25627 A1.

Claims 1-4 and 34 have been provisionally rejected for alleged obviousness-type double patenting over claims 118, 119, 120, 149 and 150 of copending Application No. 10/167,652 in view of WO 94/25627 A1.

Claims 1-5 and 34 have been provisionally rejected for alleged obviousness-type double patenting over claims 174, 197-200, 217 and 230-232 of copending Application No. 09/985,809 in view of WO 94/25627 A1.

Claims 1-5 and 34 have been rejected for alleged obviousness-type double patenting over claim 1 of U.S. Patent No. 7,056,689 in view of WO 94/25627 A1.

The double patenting rejections are respectfully traversed. In the claimed method the virus is administered in two or more desensitization doses followed by one or more escalated doses, wherein the amount of the virus in the second and any subsequent desensitization dose is greater than the amount of the virus in the preceding desensitization dose, and the amount of the virus in each of the one or more escalated doses is higher than the amount of virus in each of the desensitization doses. Thus, the claimed invention utilizes at least two dose levels for desensitization (two-step desensitization) followed by a further escalated dose, for a total of at least three sequentially increasing dose levels. The claims that form the basis of the double patenting rejections are not directed to a regimen that utilizes two-step desensitization prior to the escalated dose(s). As illustrated in Example 2 of the present invention, two-step desensitization resulted in fewer Grade 3 (severe) adverse events than one-step desensitization.

Applicants submit that the claimed invention is patentably distinct over the claims of the reference patents and, accordingly, the double patenting rejections have been overcome.

CLAIMED INVENTION IS NOVEL AND NONOBVIOUS

Claims 1-5, 6-9, 12, 17, 21-23, 26-30, 33, 34, 37 and 52 have been rejected under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 99/18799A1 (Lorence '99) in view of WO 94/25627A1 (Lorence '94).

Claims 1-5, 6-9, 12, 17, 21-23, 26-30, 33, 34, 37 and 52 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Pecora et al. (J. Clin. Oncol. May 2002) or, in the alternative, under 35 U.S.C. §103(a) as allegedly being obvious over Pecora in view of WO 94/25627A1 (Lorence '94).

In addition to the Section 102(b) rejection over Pecora mentioned in the preceding paragraph, claims 1-12, 17, 21-23, 33 and 34 have been rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Pecora et al. (J. Clin. Oncol. May 2002).

Claims 1-5, 6-9, 12, 17, 21-23, 26-30, 33, 34, 37 and 52 have been rejected under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) as allegedly being unpatentable over WO 00/62735A2 (Lorence '00) in view of WO 94/25627A1 (Lorence '94).

Claims 1-5 and 33-34 have been rejected under 35 U.S.C. §102(e) as allegedly being anticipated by, or, in the alternative, under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 7,056,689 in view of WO 94/25627A1 (Lorence '94).

All of the preceding rejections are respectfully traversed. Each of claims 7-8, 10-11, 33, 37 and 52 has been canceled in this or a previous amendment.

In the claimed method the virus is administered in two or more desensitization doses followed by one or more escalated doses, wherein the amount of the virus in the second and any subsequent desensitization dose is greater than the amount of the virus in the preceding desensitization dose, and the amount of the virus in each of the one or more escalated doses is higher than the amount of virus in each of the desensitization doses. Thus, the claimed invention utilizes at least two dose levels for desensitization (two-step desensitization) followed by a further escalated dose, for a total of at least three sequentially increasing dose levels. The cited references neither disclose nor in combination suggest a two-step desensitization regimen prior to the escalated dose(s). The cited references disclose, at most, only a one-step desensitization regimen. As illustrated in Example 2 of the present invention, two-step desensitization resulted in fewer Grade 3 (severe) adverse events than one-step desensitization.

Moreover, the rejection under Section 102(b) over Pecora is improper because Pecora was published in May 2002, less than one year prior to the effective filing date of the subject application. The subject application is entitled to the June 21, 2002 priority date of Provisional Application No. 60/390,632.

Applicants submit that the rejections under Sections 102 and 103 have been overcome.

CONCLUSION

Reconsideration and withdrawal of all rejections is respectfully requested.

It is believed that no fee is necessary in connection with the filing of this Amendment. If any

fee is required, the Commissioner is hereby authorized to charge the amount of such fee or to refund any overpayment to Deposit Account No. 50-1677.

Respectfully submitted,

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